American Bakers Association

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February 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 99N-2497; Citizens Petitions; Actions That Can Be Requested by Petition; Denials; Withdrawals, and referrals for Other Administrative Action; 64 Fed. Reg. 66822 (Nov. 30, 1999)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of approximately 300 bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. ABA submits comments on the agency's proposed rule that seeks to revise the citizen petition process.

ABA is seriously concerned that FDA's proposed rule would inappropriately change and set limited boundaries around the citizens petition mechanism. While the agency seeks to streamline and improve the petition process, ABA vehemently argues that the agency's proposal would in fact, severely limit industry's ability to voice its concerns and receive answers in a timely manner.

ABA understands that under the proposed rule, the agency would be permitted to treat many petitions as correspondence. Unless a petition addressed a public health or consumer protection concern; raised issues for a particular product or class of products; or raised issues that are the subject of a pending or future rulemaking, it would be remanded to informal correspondence channels. ABA strongly argues that this would not be acceptable for several reasons. On this informal track, there would be no guarantee of adequate review by high level FDA officials; no guarantee of a definitive and substantive reply to questions raised and no final agency action, therefore making it unlikely for a

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judicial review to occur. Besides correspondence, other means of communications with the agency including meetings, telephone calls, electronic mail, and faxes are also inadequate options for the same reasons listed above.

Clearly, many meaningful petitions would not be accepted, or would be treated as correspondence. Several examples of unacceptable petitions under the proposal include:

- petitions to issue or amend guidance documents;
- petitions relating to agency procedures;
- petitions to reopen administrative records in pending rulemakings;
- petitions to prevent issuance of a pending order, even if on safety grounds and
- petitions seeking clarification of FDA's position on acceptable testing standards or protocols.

Additionally in its proposal, FDA fails to give reasons for excluding petitions that clearly fall under the agency's statutory jurisdiction (i.e., economic issues; questions regarding agency procedures and financial disclosure issues). Also, FDA fails to define how it will determine if an issue will be the subject of "future administrative action"; arguably this tactic could be used to vacillate virtually any proposal to the correspondence track.

While FDA justifies its proposal based on the backlog of hundreds of petitions that the agency claims are due to frivolous petitions, repetitive petitions, petitions that request action beyond the agency's jurisdiction, petitions that pertain to matters that require legislative relief and petitions filed for improper purposes, there is no data sited in the proposal supporting the claim that these petitions drain FDA resources. In fact, the 1998 Office of the Inspector General (OIG) Report notes that it would be impossible to assess the resource drain claim because of the agency's poor record keeping of its allocation of staff and resources. Additionally, ABA notes that there is no requirement by FDA to spend inordinate amounts of time on frivolous petitions, as they are easy to identify.

In conclusion, ABA believes that this proposal will not streamline the process but potentially creates discord by providing opportunity for inconsistency from division to division within the agency. If procedural issues are resolved through private correspondence, on a case-by-case basis, there is likely to be conflicting decisions within

the agency. Additionally, this backward action moves important policy discussions from the public policy arena to private correspondence, which is completely contrary to the intent of FDAMA (which increased public participation in agency decision-making) and from "good government" legislation such as the Freedom of Information Act (FOI) and sunshine laws.

Also, ABA believes it is likely that parties, who use the citizens petitions process in lieu of litigation currently, would be forced to go straight to court under the new scenario; creating added burden on the agency.

ABA appreciates this opportunity to comment on this proposal, which is of interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

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